MEDICAL COVERAGE POLICY	
SERVICE:	**Brexucabtagene autoleucel (Tecartus™)**
Policy Number:	**281**
Effective Date:	**1/1/2025**
Last Review:	**10/14/2024**
Next Review:	**10/14/2025**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Brexucabtagene autoleucel (Tecartus™)

PRIOR AUTHORIZATION: Required

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to Medicare NCD 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

Baylor Scott & White Health Plan (BSWHP) may consider brexucabtagene autoleucel (Tecartus™) medically necessary for the treatment of mantle cell lymphoma or B-cell precursor acute lymphoblastic leukemia (ALL) **when ALL of the following universal criteria are met as well as criteria specific to each indication below:**

Universal Criteria Applied to All Requests

1. Member is ≥ 18 years old; **AND**
2. Member diagnosed by a hematologist or oncologist; **AND**
3. Brexucabtagene autoleucel will be used as monotherapy; **AND**
4. Dose and frequency should be consistent with FDA labeling or NCCN; **AND**
5. Member is eligible for apheresis; **AND**
6. Member has or will receive lymphodepleting chemotherapy (e.g., fludarabine and cyclophosphamide) before infusion of brexucabtagene autoleucel; **AND**
7. Provider attests all REMS program requirements are met; **AND**
8. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
9. Member has documentation of CD-19 tumor expression; **AND**
10. Member has NOT received prior treatment with CD-19 targeted CAR-T cell therapy; **AND**
11. If the member has received prior treatment with anti-CD19 therapy the member's repeat biopsy indicated CD-19 positive disease; **AND**
12. Member does NOT have any of the following conditions:
    a. Active hepatitis B (HBs AG-positive), active hepatitis C, HIV infection, or uncontrolled infection

b. History of central nervous system disorders (ex. seizure disorder, cerebrovascular ischemia)
c. Primary immunodeficiency
d. Pregnant

Indication Specific Criteria

Mantle Cell Lymphoma (MCL) specific criteria:

1. Member meets all universal criteria; **AND**
2. Member has at least 1 measurable lesion; **AND**
3. Member meets one of the following criteria:
   a. Member has relapsed or refractory MCL defined as disease progression after last regimen
   b. Member has refractory disease defined as failure to achieve a partial response or complete response to the last regimen; **AND**
4. Member must have received adequate prior therapy including ALL of the following:
   a. Anthracycline, bendamustine, or lenalidomide-containing chemotherapy
   b. Anti-CD20 monoclonal antibody therapy (e.g., rituximab)
   c. Bruton's tyrosine kinase inhibitor (BTKi) therapy (e.g., ibrutinib, acalabrutinib, zanubrutinib);

   AND
5. Member does NOT have any of the following conditions:
   a. Allogeneic hematopoietic stem-cell transplantation in the preceding 84 days before leukapheresis

B-cell precursor Acute Lymphoblastic Leukemia (B-ALL) specific criteria:

1. Member meets all universal criteria; **AND**
2. Member meets one of the following criteria:
   a. Member has Philadelphia chromosome (Ph)-negative B-cell precursor ALL that is relapsed or refractory defined as one of the following:
      i. Refractory to first-line therapy (i.e., primary refractory)
      ii. First relapse following a remission lasting ≤ 12 months
      iii. Relapsed or refractory ALL after second-line or higher therapy
      iv. Relapsed or refractory ALL at least 100 days after allogeneic stem cell transplantation (HSCT)
   b. Member has Philadelphia chromosome (Ph)-positive B-cell precursor ALL and meets one of the following:
      i. Member has relapsed or refractory disease despite treatment with at least two different tyrosine kinase inhibitors (TKIs)
      ii. Member is intolerant to TKI therapy
      iii. Member has a contraindication to TKI therapy

   AND
3. Member does NOT have any of the following conditions:

a. History of CNS disorders including CNS-2 disease with neurologic changes and CNS-3 disease irrespective of neurological changes
b. Active inflammatory disorder requiring systemic immunosuppression
c. Active graft versus host disease (GVHD)

Only ONE dose per lifetime is medically necessary.

BSWHP considers brexucabtagene autoleucel (Tecartus™) for the treatment of all other indications to be experimental, investigational, and/or unproven.

All requests will be reviewed by both a clinical pharmacist and a medical director.

BACKGROUND:

Chimeric antigen receptor (CAR) T cells and genetically engineered T-cell receptor (TCR T) cells are manufactured by collecting lymphocytes from a patient or donor and modifying them using gene transfer techniques. Viral vectors are introduced that express cell receptors that are highly specific for tumor antigens. CAR T and TCR T cells are then infused back into the patient where they direct a targeted immune response to cancerous tissue. CAR T cells express a hybrid receptor with an extracellular single-chain antibody fragment, a transmembrane domain, and at least 1 intracellular signaling domain. CAR T cells are most often used to treat hematological malignancies, and a common target is B-cell cluster of differentiation antigen 19 (CD19).

The U. S. Food and Drug Administration (FDA) granted accelerated approval for brexucabtagene autoleucel (Tecartus™) on July 24, 2020 for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). The indication is approved under accelerated approval based on overall response rate and durability of response and continued approval for this indication may be contingent upon a confirmatory trial. The boxed warning includes the clarification that brexucabtagene autoleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS) and neurological toxicities.

In a multicenter phase two trial, a total of 74 patients were enrolled to evaluate the safety and efficacy of brexucabtagene autoleucel. To be eligible, patients had to have MCL that had relapsed or was refractory and had previous therapy that included anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 monoclonal antibody, and BTK inhibitor therapy with ibrutinib or acalabrutinib. It was found that 85% of patients had an objective response and 59% had a complete response. Regarding estimated progression-free survival and overall survival, the percentages of patients were 61% and 83% respectively. With respect to the safety of brexucabtagene autoleucel, 99% of patients had an adverse event of grade 3 or higher with the most common types being cytopenias (94%) and infections (32%). For serious adverse events, it was found that 68% of patients experienced these types of adverse events.

In October 2021 the FDA approved brexucabtagene autoleucel for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) based on an open-label, single-arm, multicenter phase 1/2 trial. Eligible patients were adults with primary refractory ALL, first

relapse following a remission lasting ≤ 12 months, relapsed or refractory ALL after second-line or higher therapy, or relapsed or refractory ALL at least 100 days after allogeneic stem cell transplantation (HSCT). Of 71 patients enrolled and leukapheresed, 54 were efficacy-evaluable. The primary end points were the percentage of participants experiencing dose-limiting toxicities (DLTs) and overall complete remission (CR) rate. 28 (51.9%) of the 54 evaluable patients achieved a complete remission (CR) with 3 months after the infusion. No DLTs occurred in the DLT-evaluable cohort.

CODES:

Important note: *Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	36511 Therapeutic apheresis; for white blood cells
HCPCS Codes:	Q2053 Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
ICD10 codes:	C83.10-C83.19 Mantle cell lymphoma
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	11/19/2021	New policy
Updated	01/28/2021	Minor updates to criteria and excluded sections
Updated	04/22/2021	Medicaid instructions added.
Updated	05/27/2021	Removed Oncology Analytics line, added apheresis criteria, reformatted criteria
Updated	07/22/2021	Added clinician reviewer criteria
Updated	06/23/2022	Added NCD information
Updated	12/01/2022	Removed language with CMS LCD since NCD applies. Removed Texas Mandate HB1584 language from main policy section as the policy is compliant. Added criteria for ALL.
Reviewed	10/26/2023	Applied new layout and format.
Updated	10/14/2024	Reformatted with Universal and Specific criteria, Updated universal criteria to align exclusion criteria when applicable across CAR-T therapies

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and make modifications based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and

they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.